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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,412	06/02/2005	Stuart Alan McNeill	CAF-201-A	1464

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EXAMINER	
LLOYD, EMILY M	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,412	MCNEILL ET AL.	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because head portion 9, described on page 15 line 15 regarding Figure 1, is not shown in Figure 1; page 16 line 18 "pistons 15" should be "pistons 11"; Figure 2a is not described anywhere in the specification; and Figure 5 is missing the label for the x-axis title/units. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the

description: 29a. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because it exceeds 150 words and contains the word "said" numerous times. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: page 2 line 20 there should be a space in "US5785663"; page 14 lines 25, 27, and 29 the period after the figure number should be deleted; page 15 lines 8-9 should be revised for clarity; page 17 lines 9 and 11 the numbers 52 and 16 should be spelled as they are the first words in their sentences; page 19 line 16 "in known" should be "in a known"; page 19 line 30 "an current" should likely be "and current"; page 19 lines 32-33 "range of frequency of actuation is an" should be "range of frequencies of actuation in an"; and page 20 line 23 "toque" should be "torque".

Appropriate correction is required.

6. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

7. Claims 2-17 and 19-20 are objected to because of the following informalities: claims 2-17 and 19-20 should begin with "The" instead of "An"; claim 16 line 3 "in use" should be "during use"; claim 18 lines 9-10 "so as to periodically force in the range of from 0.01 N to 1 N" should be deleted; and claim 21 line 13 "ductal surface" should be "ductal surface;". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 12, it is unclear what structures and relationships between structures are being claimed. For the purpose of examination, the Examiner has interpreted claim 12 to encompass the displacement device incorporating an actuator whose position is controlled and the actuator may be used to monitor displacement of the displaceable body.

Regarding claim 16, it is unclear what line 4 "it" refers to. For the purpose of examination, the Examiner has interpreted "it" to refer to the displaceable body.

10. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, the terms "formed and arranged for"; "so as to be"; and "wherein is provided" are indefinite or grammatical errors.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent Publication 2005/0256387 (Omata).

Regarding claim 1, Omata discloses an apparatus suitable for use in investigating multi-phase biological tissue histology (elasticity measuring device 1 Figure 1), which apparatus comprises a trans-ductally deployable probe (probe base 5 Figure 1) mounting a periodically displaceable body (probe 7 Figure 1) of at least one tactile sensing device (stress detection sensor 21 Figure 1), said displaceable body being provided with a displacement device (plate spring 15 Figure 1) having a displacement controller (micro-motor [0039] lines 17-19) for controlling at least said excitation frequency, said displaceable body being coupled to a displacement monitoring device (deviation detection sensors 23 Figure 1) and a displacement force monitoring device (stress detection sensor 21 Figure 1), for monitoring the viscoelastic response of said biological tissue to periodic compression by said displacement force applied to said tissue by periodic displacement of said periodically displaceable body (elasticity calculation device 29 Figure 1).

Omata does not expressly disclose that the periodically displaceable body has an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N because Applicant has not disclosed that these measurements provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Omata's elasticity measuring device, and applicant's invention, to perform equally well with either the disclosure of Omata or the claimed frequency, stroke length, and displacement force because the claimed frequency, stroke length, and displacement force would perform the same function of applying a safe yet effective motion to a body canal equally well considering the typical material properties and sizes of body canals.

Therefore, it would have been prima facie obvious to modify Omata to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Omata.

Regarding claim 2, Omata teaches the apparatus according to claim 1 wherein said probe is formed and arranged so as to be trans-ductally deployable in at least one of the genito-urinary tract in males and females, the gastro-intestinal tract, the respiratory tract, and within the arterial and venous vasculature system (elasticity measuring device 1 Figure 1 is capable of fitting in the gastro-intestinal tract).

Regarding claim 3, Omata teaches the apparatus according to claim 1 for trans-urethral deployment, wherein and said probe has a diameter of not more than 5 mm ([0037] lines 7-8, with the sleeve 9 covering the distal end the invention would only be slightly larger than probe base 5).

Regarding claim 4, Omata teaches an apparatus according to claim 3 wherein said probe has a length of from 1 to 3 cm (probe 7 Figure 1 would be in this range given the probe diameter).

Regarding claim 5, Omata teaches the apparatus according to claim 1 wherein said displaceable body is actuated via at least one of: a pressurized fluid circuit, a mechanical drive system, and a piezoelectric actuator (micro-motor [0039] lines 17-19 is a mechanical drive system).

Regarding claim 6, Omata teaches the apparatus according to claim 1 wherein said probe is mounted at the distal end of an elongate, trans-ductally deployable, deployment device ([0037] lines 3-7).

Regarding claim 7, Omata teaches the apparatus according to claim 6 wherein said displaceable body is actuated by a proximally mounted motor ([0039] lines 17-19).

Regarding claim 8, Omata teaches the apparatus according to claim 6 wherein said displaceable body is actuated by a distally mounted motor drivingly connected to the displaceable body via said elongate deployment device ([0039] lines 17-19).

Regarding claim 9, Omata teaches the apparatus according to claim 1 wherein said displaceable body comprises at least one micro-piston actuated via a pressurized fluid circuit (stress detection sensor 21 Figure 3).

Regarding claim 10, Omata discloses an apparatus according to claim 1 wherein said displaceable body comprises at least one shoe mounted on a piezoelectric device sandwiched between said shoe and a stress detector element, formed and arranged for monitoring strain therein, thereby to determine the force applied by said displacement body to tissue contacted thereby in use of said apparatus (Omata teaches stress detection sensor 21 adjacent contact ball 19 of a known surface area; a stress detection sensor with a known area is equivalent to a force sensor).

Regarding claim 11, Omata teaches the apparatus according to claim 1 wherein at least one of the area of the force-transmitting surface of the displaceable body, used to apply force to the tissue in use of the apparatus, and the magnitude of the force applied to the displaceable body, is formed and arranged so as to be user-adjustable ([0039] lines 17-19 the length and speed of the movement of sleeve 9 and probe base 5 relative to each other would determine the area of the surface applied to the tissue and the magnitude of the force).

Regarding claim 12, Omata teaches the apparatus according to claim 1 wherein said displacement device incorporates an actuator whose position is controlled (micro-motor [0039] lines 17-19) and the actuator may be used to monitor displacement of the displaceable body.

Regarding claim 13, Omata teaches the apparatus according to claim 1 wherein a force detector is incorporated in at least one of the displaceable body displacement controller, the force source, and the displaceable body itself (stress detection sensor 21 in displaceable body/contact ball 19 Figure 1).

Regarding claim 14, Omata teaches the apparatus according to claim 1 wherein is provided a displacement controller formed and arranged for application of selected ones of plurality of different excitation frequencies ([0039] lines 17-22).

Regarding claim 15, Omata teaches the apparatus according to claim 1 wherein is provided a displacement controller formed and arranged for controlling each of said excitation frequency and stroke length (micro-motor [0039] lines 17-19 inherently has a controller).

Regarding claim 16, Omata teaches the apparatus according to claim 1, which includes a position control device for changing the position of the displaceable body within a body duct, in use of the apparatus, so as to successively bring it into contact with a plurality of different duct surface portions (Figure 6).

Regarding claim 17, Omata teaches the apparatus according to claim 1 which includes a processing unit formed and arranged for processing displacement and displacement force data (elasticity calculation device 29 Figure 1) so as to generate at least one of dynamic modulus and Amplitude Ratio.

Regarding claim 18, Omata discloses a method for producing a histological profile of a biological tissue adjacent a duct comprising the steps of: a) providing an apparatus according to claim 1 (Figure 1; see rejection of claim 1 above); b) transductally inserting the probe of said apparatus to bring the periodically displaceable body of said probe into contact with the ductal surface of said biological tissue at a plurality of positions across said ductal surface (Figure 6); c) subjecting said displaceable body to a periodic displacement so as to periodically compress said

biological tissue at said contact positions across said ductal surface ([0039] lines 13-19); d) monitoring the viscoelastic response of said tissue at each of said surface contact tissue positions to compression by said body (Figure 6); and e) generating a profile of the viscoelastic response of the tissue across said ductal surface (elasticity calculation device 29 Figure 1; Figure 6).

Omata does not expressly disclose that the periodically displaceable body has an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N because Applicant has not disclosed that these measurements provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Omata's elasticity measuring device, and applicant's invention, to perform equally well with either the disclosure of Omata or the claimed frequency, stroke length, and displacement force because the claimed frequency, stroke length, and displacement force would perform the same function of applying a safe yet effective motion to a body canal equally well considering the typical material properties and sizes of body canals.

Therefore, it would have been prima facie obvious to modify Omata to obtain the invention as specified in claim 1 because such a modification would have been

considered a mere design consideration which fails to patentably distinguish over the prior art of Omata.

Regarding claim 19, Omata teaches the method as claimed in claim 18 which includes the preliminary step of determining values of displacement frequency, displacement stroke length and displacement force suitable for histological profiling of the type of biological tissue to be profiled (it is well known in the art to adjust devices to the size and health of the patient, as well as the part of the patient that is being examined; for example, otoscopes come with different attachments for different size ears and noses).

Regarding claim 20, Omata teaches the method as claimed in claim 18, wherein said displacement body is contracted with a said plurality of tissue surface contact positions, which plurality is distributed axially and/or circumferentially of said duct ([0038] lines 20-21).

Regarding claim 21, Omata discloses a method of diagnosing a condition manifested by a histological abnormality in biological tissue adjacent a body duct comprising the steps of: a) providing an apparatus according to claim 1 (Figure 1; see rejection of claim 1 above); b) trans-ductally inserting the probe of said apparatus to bring the periodically displaceable body of said probe into contact with the ductal surface of said biological tissue at successive ones of a plurality of positions across said ductal surface (Figure 6); c) subjecting said displaceable body to a periodic displacement so as to periodically compress said biological tissue at said contact positions across said ductal surface ([0039] lines 13-19) d) monitoring the viscoelastic

response of said tissue at each of said tissue surface contact positions to compression by said body (Figure 6); e) generating a profile of the viscoelastic response of the tissue across said ductal surface (elasticity calculation device 29 Figure 1; Figure 6); and f) comparing said generated viscoelastic response profile with viscoelastic response profiles of such tissue having known histological characteristics ([0005] lines 17-22 and [0006]).

Omata does not expressly disclose that the periodically displaceable body has an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an excitation frequency bandwidth in the range of from 1 Hz to 500 KHz, a maximum stroke length of less than 1 mm and a displacement force in the range from 0.01 N to 1 N because Applicant has not disclosed that these measurements provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Omata's elasticity measuring device, and applicant's invention, to perform equally well with either the disclosure of Omata or the claimed frequency, stroke length, and displacement force because the claimed frequency, stroke length, and displacement force would perform the same function of applying a safe yet effective motion to a body canal equally well considering the typical material properties and sizes of body canals.

Therefore, it would have been prima facie obvious to modify Omata to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Omata.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd

Examiner
Art Unit 3736

/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736